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IN THE

Supreme Court of the United States

APOTEX CORP.,
Petitioner,

v.

MERCK & CO., INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF OF THE PETITIONER

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CORPORATE DISCLOSURE STATEMENT

As stated in the petition, and pursuant to this Court's Rule 29.6, petitioner Apotex Corporation states that it is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in Weston, Florida and is a subsidiary of Aposherm, Inc., a corporation organized and existing under the laws of Canada. No publicly traded company owns 10% or more of Apotex's stock.

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APOTEX CORP.,

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Respondent.

Merck's Brief in Opposition ("Br.") contains quite astonishing mischaracterizations of the Third Circuit's decision in *Herring v. United States*, 424 F.3d 384 (3d Cir. 2005), and this Court's decision in *Brotherhood of Locomotive Engineers v. Missouri-Kansas-Texas R.R. Co.*, 363 U.S. 528 (1960). When these are put aside, it is plain that this case merits plenary review.

1. Merck observes that *Herring* involved a motion to dismiss a complaint in an independent action seeking relief from a judgment on the basis of fraud, and while acknowledging that the Third Circuit "reviewed [the district court's decision] under the *de novo* standard" (Br. 10) claims that "if the Third Circuit in *Herring* were instead reviewing the district court's disposition of the Rule 60(b) allegations on the merits (*i.e.*, disposition of the merits of an action seeking equitable relief), the Third Circuit would have instead reviewed under the abuse of discretion standard." *Id.* at 10–11. This account — conflating as it does an independent action with a motion for relief from

judgment under FED. R. CIV. P. 60(b) — cannot be reconciled with *Herring* itself.

In *Herring*, the court took pains to note that "an independent action alleging fraud on the court is completely distinct from a motion under Rule 60(b)." 424 F.3d at 389. For that reason, the court rejected the argument that because "determinations based on Rule 60(b) are reviewed only for abuse of discretion, an independent action for fraud should be reviewed at least as deferentially." *Id.* Instead, the court held that independent actions should be adjudicated "without altering the Federal Rules of Civil Procedure," and therefore employed "the normal *de novo* review that applies to a district court's grant of a Rule 12(b)(6) motion to dismiss . . . ." *Id.* This case involves review of a district court's summary judgment ruling, rather than a motion to dismiss, but as we explain in the petition, it is settled that summary judgment rulings, like rulings on a motion to dismiss, are reviewed *de novo* on appeal. (*See* Pet. 15.) Thus, *Herring* calls for *de novo* review here because that is the ordinary approach to review of summary judgment rulings under the Federal Rules of Civil Procedure. The more limited review of a Rule 60(b) ruling, *Herring* explains, has no place in an independent action.

Accordingly, it is evident that if a litigant in the Third Circuit forwarded Merck's argument that appellate review of a summary judgment ruling in an independent action alleging fraud on the court should be governed by Rule 60(b) standards, that litigant would be stopped short by *Herring*'s refusal to apply Rule 60(b) standards to independent

actions. While, as we acknowledge in the petition, a number of circuits, including the court below, have conflated Rule 60(b) motions and independent actions, the Third Circuit has emphatically refused to do so. (*See* Pet. 12–15.) The conflict in the circuits is patent.

2. Merck claims that *Brotherhood of Locomotive Engineers* settled that "appellate review of a district court's denial of equitable relief occurs under the abuse of discretion standard." (Br. 9.) This is a truly remarkable misuse of that decision.

In *Brotherhood of Locomotive Engineers*, the respondent railroads unilaterally altered their work rules, and, after a hearing, the district court enjoined the resulting strike pending a hearing before the National Railroad Adjustment Board but required the railroads to either rescind the changes or pay the affected employees the wages they would have received under the old rules. *See Brotherhood of Locomotive Engineers v. Missouri-Kansas-Tex R. Co.*, 363 U.S. 528, 529–30 (1960). In that context, the Court wrote: "The balancing of . . . competing claims of irreparable hardship is . . . the traditional function of the equity court, the exercise of which is reviewable only for abuse of discretion." *Id.* at 534–35. This holding was unremarkable; a long line of cases holds that a district court has broad discretion in fashioning equitable relief that is reviewable on appeal only for abuse of discretion. *See, e.g., eBay, Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 391 (2006). But, as should be plain, Merck's reliance on *Brotherhood of Locomotive Engineers* in this case is doubly inapposite — *Brotherhood of Locomotive Engineers* involved the

scope of a district court's discretion when granting equitable relief, not denying it, and it dealt with the deference owed a district court's decision to fashion a remedy after an evidentiary hearing, not with the standard applicable to review of a district court's summary judgment ruling.

As we explain in the petition, it is settled that a district court's decision to grant summary judgment is reviewed on appeal *de novo*. (*See* Pet. 15.) Nothing in *Brotherhood of Locomotive Engineers* — which was simply not a summary judgment case — is inconsistent with this rule, nor is there any exception to the rule of *de novo* appellate review of summary judgment for cases seeking equitable relief. Indeed, one of the cases we cite on this point in the petition involved a request for equitable relief — *Agosto v. INS*, 436 U.S. 748 (1978), was an action to set aside an order of deportation. *See id.* at 750–52. This is but one of many cases applying *de novo* appellate review to summary judgment rulings in actions seeking equitable relief. *See, e.g.*, *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (action alleging a merger violated section 7 of the Clayton Act). There is simply no support for Merck's assertion that summary judgment rulings are reviewed deferentially in actions seeking equitable relief.

In any event, even if Merck were correct that summary judgment rulings in actions seeking equitable relief should be reviewed deferentially on appeal, this case was not confined to a request for equitable relief. Apotex's complaint contained common law fraud and tortious interference with business relationship counts and expressly sought

damages. Docket Item 26, *First Amended Complaint* at 13–16, (N.D. Ill. No. 04-CV-07312) (attached in the Appendix to this brief, Reply App. 24a–25a)

3. Merck argues that if appellate review in independent actions alleging fraud on the court were subject to ordinary summary judgment rules and *de novo* appellate review, no one would file Rule 60(b) motions for relief from judgment because it would be easy to circumvent the timeliness and other limitations imposed by Rule 60 by filing an independent action. (*See* Br. 11.) Of course, the plain language of Rule 60 envisions the independent action as an alternative to seeking relief under Rule 60 — that is the unmistakable import of Rule 60(d)'s savings clause, as we explain in the petition. (*See* Pet. 17–18.) If Merck were correct that an independent action is subject to precisely the same rules as a motion for relief under Rule 60, the savings clause would be a pointless exercise in surplusage.

In any event, what Merck brands "an absurd result" (Br. 11) fails to take account of the higher standard that confronts plaintiffs in an independent action. To ensure that independent actions do not circumvent the limitations on Rule 60 relief, the proper approach is not to ignore its savings clause, but to set the bar for relief in an independent action appropriately high. As this Court has explained: "Independent actions must, if Rule 60(b) is to be interpreted as a coherent whole, be reserved for those cases of 'injustices which, in certain instances, are deemed sufficiently gross to demand a departure' from rigid adherence to the

doctrine of res judicata." *United States v. Beggerly*, 524 U.S. 38, 46 (1998). Indeed, in *Herring*, the Third Circuit rejected the same argument that Merck now forwards, stating: "We are quite capable of taking full account of the narrow criteria for relief present in an independent action for fraud upon the court without altering the Federal Rules of Civil Procedure." 424 F.3d at 389.

4. Merck finally argues that under any standard of review, Apotex's allegations of fraud are wanting. (*See* Br. 12–13.) This assertion is belied not only by the record, but by the assessment of the Federal Circuit itself in a related case when it considered the very same evidence on which we now rely, but without the circumscribed standard of appellate review that it erroneously applied to this case.

In the original action between Apotex and Merck, as part of its motion seeking summary judgment on the ground that Apotex's patent was invalid because Merck had previously made the same invention and not "abandoned, suppressed, or concealed it" within the meaning of 35 U.S.C. § 102(g), Merck told the district court that it had not suppressed or concealed its process for making VASOTEC® tablets because it had published the ingredients as early as 1992 in its product monograph and in the 1988 edition of the *Dictionnaire Vidal*, and because Brian McLeod had described in open court the "details" of "Merck's process for making VASOTEC® tablets" during the Canadian litigation, which Merck characterized as an "unrestricted disclosure," adding that its "conduct in the late 1980s and early 1990s belies

any intention to keep its product secret." (Pet. App. 16a.) On just this basis, the district court ruled that Merck had not suppressed or concealed the invention because the ingredients for VASOTEC® were publicly available, and because Mr. McLeod's Canadian testimony and accompanying videotape "explained the process in detail," and Merck had "fully disclosed the ingredients and the process" in a way that was sufficient to show a person of ordinary skill in the art how to duplicate the process. (Pet. App. 15a.) On appeal, Merck again stated that it had not suppressed or concealed its invention because it had published the ingredients for the tablets; because it had made a detailed disclosure of Merck's entire process for making its tablets in the Canadian litigation; and because the VASOTEC® process could be reverse engineered simply by examining the tablets themselves and knowing the ingredients. (Pet. App. 16a.) Affirming the district court, the Federal Circuit concluded that Merck had "disclosed the ingredients used in manufacturing VASOTEC® tablets," and also "provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994." *Apotex U.S.A., Inc. v. Merck & Co.*, 254 F.3d 1031, 1040 (Fed. Cir. 2001).

Years later, Warner-Lambert sued generic drug maker Teva Pharmaceuticals for infringement of its patented ACE inhibitor drug Accupril and Teva defended on the ground that the Accupril patent was obvious in view of Merck's pre-existing VASOTEC® tablet. *See Warner-Lambert v. Teva Pharmaceuticals USA, Inc.*, No. Civ.A. 99-922DRD, 2004 WL 1498162, *14 (D.N.J. June 29, 2004), *aff'd*

in part & rev'd in part, 418 F.3d 1326 (Fed. Cir. 2005). In that case, Merck's witness in the original Apotex case, Dr. Brenner, testified that Merck's top executives had decided to forego patent protection for VASOTEC® in favor of trade secret protection, knowing that the manufacturing process could **not** be reverse engineered through a physical examination of the VASOTEC® tablets or knowledge of the ingredients. (*See* Pet. App. 16a–17a.) Based on that testimony, the district court found that Merck had "made a deliberate decision to forego patent protection and instead to conceal from the public as a trade secret its process for stabilizing VASOTEC® using sodium bicarbonate;" that Merck was successful in "maintaining the process as a trade secret to the late 1980's or early 1990's;" and that Merck made "continuing efforts" during the 1994 Canadian litigation (on which Merck had convinced the district court and Federal Circuit to so heavily rely in the earlier Apotex case) "to withhold the role of sodium bicarbonate in that process." *Id.* at *20. On appeal, the Federal Circuit took the same view of the evidence, concluding that Merck "chose to retain the sodium bicarbonate stabilization process as a trade secret and to forego patent protection" because Merck "concluded that the competitors would not be able to figure out the process for making VASOTEC® from its ingredients alone – namely, the process used to stabilize enalapril against cyclization." *Warner-Lambert v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326, 1331 (Fed. Cir. 2005).

As the *Warner-Lambert* litigation demonstrates, when the Federal Circuit was not circumscribed by a deferential standard of

appellate review, it found the same testimony on which Apotex relies on this case demonstrated that Merck had made a conscious decision to conceal its manufacturing process for VASOTEC®. Applying the proper summary judgment standard in this case, a court could readily conclude that Merck's entire defense in the original litigation with Apotex was a fraudulent sham inconsistent with their strenuous and calculated efforts at concealment throughout the 1980s and 1990s — precisely the kind of conduct that would satisfy the concededly demanding standard for establishing fraud in an independent action.

To be sure, the justification for plenary review in this case does not depend on how the case would come out under the correct standard of appellate review. In our petition, we present for review only the question whether the court of appeals employed the correct standard of appellate review. Should the Court conclude that *de novo* review is proper, the Court would most likely remand this case to the court of appeals to apply the correct standard; the Court's general practice is not to decide in the first instance questions that have not yet been reached by the court of appeals. *See, e.g., Gonzalez v. Duenas-Alvarez*, 549 U.S. 183, —, 127 S. Ct. 815, 822–23 (2007); *Engine Manufacturers' Association v. South Coast Air Quality Management District*, 541 U.S. 246, 268–69 (2004); *West v. Gibson*, 527 U.S. 212, 223 (1999); *NCAA v. Smith*, 525 U.S. 459, 469–70 (1999). As we explain above, the conflict in the circuits over the proper standard for appellate review in an independent action merits plenary review; the question of how this case would turn out under the proper standard, in contrast, is of

little concern to anyone other than the parties. But to the extent that the strength of the evidence matters here, the Federal Circuit's own assessment in the *Warner-Lambert* litigation of the same evidence on which we rely here surely demonstrates that there is in this case a compelling showing of fraud.

CONCLUSION

For the preceding reasons, the petition for a writ of certiorari should be granted.

Respectfully Submitted,

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APPENDIX

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MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX CORP.,	)	
	)	No. 04C 7312
Plaintiff,	)	
	)	Judge Matthew F.
vs.	)	Kennelly
	)	
MERCK & CO., INC.,	)	
	)	PLAINTIFF DEMANDS
Defendant.	)	TRIAL BY JURY

FIRST AMENDED COMPLAINT

Apotex Corp. ("Apotex"), by its attorneys, for its First Amended Complaint against Merck & Co., Inc. ("Merck") alleges as follows:

1. This is an action by Apotex against Merck for relief from judgment entered by this Court in matter number 96 C 7375, for common law fraud, and for tortuous [sic, tortious] interference with prospective business advantage.

Parties, Jurisdiction and Venue

2. Apotex Corp. is a Delaware Corporation that maintains offices within this district.

3. Merck & Co., Inc., is a New Jersey company, whose principal offices are located at One Merck Drive, Whitehouse Station, New Jersey.

4. This action arises under the patent laws of the United States, Title 35, United States Code, and the Federal Rules of Civil Procedure Rule 60(b) as well as the laws of the State of Illinois. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§§§ 1331, 1332, 1338 and 1367.

5. Defendant is subject to personal jurisdiction in this judicial district.

6. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

Statement of Facts Common to All Counts

7. Apotex realleges paragraphs 1 through 6 above as if fully set forth herein.

8. On November 12, 1996, Apotex filed a Complaint against Merck alleging infringement of two United States Patents, USP 5,573,780 and USP 5,690,962 ("the Apotex patents"). Both patents were assigned to Apotex. That case became known as

Apotex USA, Inc. v. Merck & Co. Inc., Case No. 96 C7375 ("the 7375 action") in this district.

9. The Apotex patents disclosed the use of alkaline sodium compounds along with a certain amount of water, neither too much water nor too little water, to cause a chemical reaction with enalapril maleate which would lead to a stable dosage form of enalapril in a tablet or solid composition. The preferred embodiments used in the Apotex patents used either sodium carbonate or sodium bicarbonate.

10. Merck answered the Complaint in the 7375 action on January 2, 1997 and served a Counterclaim on Apotex. On June 8, 1998, Merck filed a motion and memorandum seeking summary judgment that the Apotex patent was invalid for derivation and inequitable conduct. On December 28, 1998, the motion for summary judgment was denied.

11. On March 12, 1999, Apotex filed a motion for summary judgment in the 7375 action alleging that Merck infringed the Apotex patents. On April 16, 1999, Merck responded to Apotex's motion and filed its own motion for summary judgment of noninfringement of the Apotex patents.

12. On November 17,1999, Merck filed a motion for summary judgment in the 7375 action that the Apotex patents were invalid under 35 U.S.C. Section 102(g) in that Merck was the first inventor of the patented process and had not suppressed, concealed or abandoned the invention of the patents. A copy of that motion is attached as Exhibit 1. In support of

the motion in the 7375 action, Merck also filed the Declaration of Gerald S. Brenner, Ph.D., a former Merck employee. A copy of the Brenner declaration is attached as Exhibit 2.

13. The Brenner declaration in the 7375 action stated that Brenner who had a Ph.D. in organic chemistry (paragraph 3) worked for Merck from 1961 through 1994 (paragraph 4). It further stated that he was involved with the development for the process of manufacturing enalapril maleate tablets (paragraph 4). Brenner further declared that Merck developed the process in the early 1980's, that the Merck Frosst's Product Monograph for Vasotec contained an accurate identification of the ingredients used in that process, that McLeod's testimony on March 28,1994 (in an earlier Canadian infringement trial between Apotex and Merck) provided an accurate summary explanation of the steps for making the product and that the process that Merck used was still being used to make its enalapril maleate tablets (paragraphs 5 and 6).

What Merck purposely and with the intent to defraud Apotex and the Court withheld from the Brenner declaration was that Merck decided to maintain the critical role of sodium bicarbonate in the process for making its enalapril maleate tablets as a trade secret; that, in fact, Merck maintained it as a trade secret at least to the early nineties; and, that, in fact, Merck knew that even knowing the ingredients in the tablets would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril maleate tablets, and without knowing that critical role, persons in the art would

not be informed as to Merck's process for making the stable enalapril maleate tablets.

14. On January 20, 2000, the Honorable Judge Matthew F. Kennelly, issued a Memorandum Opinion in the 7375 action ruling on Merck's motion for summary judgment of invalidity. In that decision, without knowing the facts that had been purposefully kept out of the Brenner declaration, the Court found, "Nor do the facts of this case suggest that Merck deliberately suppressed or concealed its invention." (Exhibit 3, page 14.) The Court found that the product monograph, Dictionnaire Vidal, and the disclosure at the Canadian infringement trial, "taken together" clearly and convincingly established that Merck did not intentionally suppress or conceal its invention." Based on this, the Court in a grave miscarriage of justice found that Merck had "neither abandoned, suppressed nor concealed that process," and entered judgment against Apotex invalidating the Apotex patents.

15. As part of the Court's ruling in the 7375 action, the Court found, based on Merck's arguments and material omissions, that the Apotex patents were invalid. As such, in a grave miscarriage of justice, Merck through its material omissions caused Apotex to lose the Apotex patents.

16. On February 3, 2000, without knowledge of the material omissions from the Brenner declaration and without the ability to know of the material omissions, Apotex filed a motion for reconsideration in the 7375 action.

17. On March 17, 2000, the Court denied the motion for reconsideration in the 7375 action by stating in part:

> "So the Court is left with the disclosure of the process through McLeod's testimony in the Canadian litigation in 1994, through the product monograph and through the Dictionnaire Vidal entry, plus the fact that Merck has been using the process commercially since 1983. The Court remains convinced that these disclosures clearly and convincingly prove Merck neither suppressed nor concealed its invention." (Exhibit 4.)

The Court did not and could not have known when it entered judgment against Apotex based on the material omissions from the Brenner declaration that Merck had kept the critical role of the sodium bicarbonate a trade secret and that:

> "It was the feeling within Merck having access to only that data, that was insufficient to teach somebody the role of sodium bicarbonate in the stabilization of the formulation." (Exhibit 5, Brenner May 3, 2004 trial testimony in the U.S.D.C. for the District of New Jersey case of *Warner Lambert Co. v. Teva Pharmaceuticals USA and Schwartz-Pharma. Inc.*, at pp. 164–65.)

18. On March 21, 2000, Apotex appealed the decision in the 7375 action.

19. During the briefing in the Federal Circuit, Merck never disclosed the material omissions from the Brenner declaration, but instead continued to argue to the Court of Appeals that the product monograph (which Merck also stated applied to the Dictionnaire Vidal), a public document, disclosed all the ingredients used in the formulation steps that Mr. McLeod set out on March 28, 1994.

20. Again, without knowing of the material omission by Merck, the Federal Circuit on June 8, 2001, caused a grave miscarriage of justice when it affirmed the District Court's opinion finding the Apotex patents invalid. (254 F.3d 1031 (Fed .Cir. 2001)). (Exhibit 6.) The Federal Circuit as a basis for its decision stated:

> "Merck made several disclosures following its period of suppression or concealment that made the invention publicly known, all of which took place before Apotex's entry into the field (here, Dr. Sherman's alleged conception in April of 1994). First, Merck disclosed the ingredients used in manufacturing VASOTEC® tablets in the 1988 edition of the Dictionnaire Vidal. It also widely distributed the product monograph in Canada from October 1992 through 1994, which similarly disclosed the ingredients it used in its manufacturing process. Merck also provided a step-by-step description of the process through the testimony given by Brian McLeod at the Canadian trial on March 28, 1994. . . . Merck's various disclosures, in conjunction

with Apotex's admissions, therefore clearly and convincingly prove that Merck made the knowledge of its invention available to the public, thereby satisfying its burden of rebutting Apotex's evidence of suppression or concealment." (254 F.3d 1031 at 1040, rehearing and rehearing en banc denied, cert denied.)

The Federal Circuit would not have found the patents invalid if it knew that Merck through its material omissions had kept from the Court and Apotex the fact that it had maintained the critical role of sodium bicarbonate a trade secret and omitted critical parts of the manufacturing process from the McLeod testimony.

21. On May 3, 5–6, 2004, in the United States District Court for the District of New Jersey, Gerald Brenner appeared as a witness in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA, and Schwarz-Pharma, Inc.* (the New Jersey action). Mr. Brenner's testimony is attached as Exhibit 5. Mr. Brenner, as noted by the trial court in the New Jersey action, had appeared as both Warner-Lambert's expert and Merck' 30(b)(6) representative on the topic of Merck's enalapril maleate tablets. (289 F. Supp. 2d 515, 535 (D.N.J. 2003)) Among the statements made by Mr. Brenner under oath concerning Merck's decision to maintain the critical role of sodium bicarbonate in its process for making Vasotec® as a trade secret were the following:

Q More specifically, Dr. Brenner, following the introduction of Vasotec in the

market place, did Merck decide to maintain the role of sodium bicarbonate in its process as a trade secret?

A Yes, it did. (Exhibit 5, page 156, lines 5–9.)

Q How long did Merck maintain its Vasotec process in the role of sodium bicarbonate in that process as a trade secret?

A I would say at least to the late eighties or early nineties. (Exhibit 5, page 156, lines 10–14.)

Q Was there any consensus at Merck at that time period regarding whether people in the field could discern Merck's process for the role of sodium bicarbonate in that process from this reference? [sic]

A The consensus within Merck was that knowing the ingredients themselves, the typical work in the field could not discern the process by which Merck made Enalapril tablets.

Q And do you know that fact from your discussions regarding whether to maintain that process as a trade secret?

A That was part of the discussion that went on relative to maintaining it as a

trade secret, and the consensus opinion was that knowing the composition alone would not have allowed the preparation tablets [sic]. (Exhibit 5, pages 157–8, lines 17–06.)

A The consensus opinion was that in just examining the tablets or analyzing the tablets, one would not be able to discern the process by which we prepared the tablets. (Exhibit 5, page 158, lines 17–20.)

Q And was there a consensus within Merck regarding whether people in the field could discern how to stabilize Vasotec or determine the role of sodium bicarbonate somehow in Vasotec from this package insert?

A The individuals involved in discussions within Merck were fairly confident that knowing the ingredients one would not be able to develop a stable product. (Exhibit 5, pages 161–2, lines 24–07.)

Q Can you explain why Merck felt that way? Why didn't Merck feel that the various threats [sic] of information you've identified now, Bolvadeer, the tablets, the package insert, in the Dictionnaire Vidal would not tell one in the field the role of sodium bicarbonate in the Vasotec process, and how to use that to stabilize Vasotec?

A Well, basically, you know, at that point in time when Merck decided to keep this as a trade secret, all of those individuals, mostly myself and two other individuals in the department were aware of perhaps around five years of work that had been done on Enalapril, the magnitude of the work, and the difficulty of stabilizing the tablet. And with that realization in hand, the three onus were essentially, were the primary movers in making that decision, felt that with the experience and the knowledge of the difficulty in developing the process, the ingredients, themselves, wouldn't be sufficient to develop the process without the kind of experimentation that we had to do over a long period of time. (Exhibit 5, page 165, lines 04–24.)

Q Dr. Brenner, in deciding to protect the Vasotec stabilization process in the role of sodium bicarbonate in that process, it's a trade secret [sic]. Merck expressly decided to forgo patent protection in its process. Correct?

A Yes, they did.

Q And that's a risky decision, isn't it?

A It's a risky decision. And those onus who were discussing that at the time weighed both options, and decided that

it would be in Merck's benefit to maintain it as a trade secret. (Exhibit 5, pages 166–167, lines 22–07.)

Q Now, can you identify the timeframe when you first became involved in the Enalapril project?

A It was in the early 1980s.

Q Now, did your involvement with the Enalapril formulation end at some point in time?

A It practically followed me until the day I retired. (Exhibit 5, page 590, lines 5–10.)

Q And now, Dr. Brenner, this chemical mechanism that you described as your working hypothesis to stable Enalapril, did you eventually come up with a manufacturing process to accomplish stabilization in accordance with that working hypothesis?

A Not directly.

A And there was a process in -- a process of time? Yes. It turned out to be much more complex. (Exhibit 5, pages 608–9, lines 19–01.)

Q Okay. Now, Dr. Brenner, once you discovered the existence of this reaction

by which you could stabilize Enalapril, you described that that wasn't the end, you have your problems; correct?

A Correct.

Q And why didn't discover the reaction, solve the problem of manufacturing a stable product of Vasotec?

A Because to really solve the problem one had to insure that the reaction took place, and we're really — we're fighting an uphill battle because we really don't have a lot of water in the wet granulation. And over time we continued to learn — as we are trying to develop this process, we were — it was a learning curve almost over a three-year period. The concept worked but to get it to work on the — on a repeatable way was very difficult. And we were learning all during maybe a two- or three-year period factors which impacted on how well that neutralization reaction worked. (Exhibit 5, page 610, lines 06–25.)

Q Now, why did you care about those other acid groups if you only want to get number 2 to lead?

A Because it can't go directly to number 2. If you're adding an agent like sodium

bicarbonate, the most acidic acid in the molecule is going to be converted first.

Q Okay.

A So we have to add enough sodium bicarbonate to fully satisfy this hydroxyl group before this one will start to be converted to the NA group.

Q And so you had to use enough sodium bicarbonate to get number 1 converted before you could get to the OH group that you're interested in?

A Right. And that's implied by this 2, 2 meaning that we had to add two parts of sodium bicarbonate for each one part of Enalapril maleate. One part of sodium bicarbonate wouldn't have been enough.

Q And the process of coming to this understanding, did that take sometime?

A Quite a bit. As I said, even before we could work on this working hypothesis we had to learn something about the order of conversion. So you couldn't have even started those experiments. Once we did those experiments, then we had an idea of the amount of sodium bicarbonate to add relative to Enalapril. This was an extremely time consuming process from the standpoint of getting first all of the background chemistry

under our belt and then going on to doing experiments to really prove the concept. So ultimately we did approve of concept experiments, and did show that neutralization of these two hydroxyl groups and converting them to this form here, which would be the ONA group on one of the maleic acids; and the converting Enalapril to Enalapril sodium, we did approve of concept study in which a wet granulation was used, two parts of sodium bicarbonate was used to one part of Enalapril, and that formulation gave us the first glimmer that we were approaching the solution to the problem. (Exhibit 5, pages 612–13, lines 07–20.)

Q And now on the screen is Plaintiffs demonstrative 20, can you explain what that is?

A These were some of the impacts that we learned over time would play an impact on whether the dosage form was stable or unstable. And I can read them off. The type of mixing equipment, the duration of mixing, the temperature of mixing, the holding time of the mixer before the wet granulation is dried, and the particle size of the sodium bicarbonate used in the process.

Q And now, was there a common element to all these factors that was found to be important with respect to stability?

A The common factor, and the success of the tablet that was manufactured, depended on the extent of the reaction. By that I mean if the reaction was complete, it was a hundred percent reaction. If it was incomplete, there could be anything from zero to ninety percent a reaction. The common threat in terms of correlating stability with these factors we learned over time was how far that reaction went, converting the OH group to the NA group. (Exhibit 5, page 617–18, lines 08–03.)

Q And now let's skip down, or if you want to talk about the temperature of mixing and duration of mixing together, how do those process variability affect the stability of Vasotec?

A Both of those factors, the longer the duration and the higher the temperature of mixing, the more complete the reaction was. And in terms of the total effort that was done in this program, I had indicated before, it was a very significant effort, the kind of experiments that we did that took so much time is like, we would make tablets mixings at maybe 15 minutes, 30 minutes, one hour, and two hours.

All of those tablets would be compressed and made into tablets and their stability study. Same thing with temperature mixing. We would run maybe mixed studies at room temperature, 40 degrees, 60 degrees, 80 degrees, and all of those experiments took extremely long periods of time to do and a lot of analytical support.

Q And now the various studies that you had to do to figure out the proper ranges for these five factors, aren't those just the type of normal experimentation one encounters when scaling up from the lab to the manufacturing plant?

A Definitely not. Typically in a normal product one would never look at the temperature of mixing. Most products are mixed at room temperature. This particular product is mixed at 80 degrees, which is almost 60 degrees centigrade over room temperature.

Q And is that unusual?

A Very unusual. I personally have no experience with any formulation being granulated and mixed at 80 degrees, so this is very A typical. [sic] (Exhibit 5, pages 619–20, lines 04–10.)

Q And would you give me Plaintiffs demonstrative 21, please. And now you

talked about the fact that extent of reaction is important. Is there anything in this document that supports that?

A This document is very supportive of that. I can read it off if you would likely much. [sic]

Q Okay.

A It's difference in the granulating step for Vasotec, from the typical wet granulation process is the chemical reactions evolved, the active ingredient, Vasotec, Enalapril maleate, needs to be neutralized by sodium bicarbonate, during granulating. Previous studies have shown that the drug stability strongly depends on the extent of reaction. (Exhibit 5, pages 621–22, lines 16–04.)

Q Okay. Are there any other reasons you want to explain to the Court why one could not reverse engineer the tablets to determine Merck's Vasotec process?

A I read off at least five factors that we determined were critical in the extent of the reaction. Quite a number of those factors could never be determined by reverse engineering.

Q And can you explain that a little bit, please.

A This is a unique formulation that it's wet granulated at 80 degrees. In my 25 years at Merck, I don't remember another granulation that's granulated at 80 degrees. You could not gain that information by looking at the tablet.

Q And that temperature was important to the stabilization process; is that correct?

A It enhanced the extent of reaction.

Q Okay. Now, Dr. Brenner, to your knowledge as of 1994, had Merck ever disclosed any element of its process or the role of sodium bicarbonate in that process publicly?

A Not that I'm aware of.

Q And as of 1994, when you left the company, were you aware of anyone in the industry that had figured out either the process or sodium bicarbonate's role in that process?

A Not that I'm aware of.

22. In reliance on the statement of facts by Brenner, which facts had been intentionally omitted by Merck from the Brenner declaration attached to Merck's motion for summary judgment in the 7375 action, the Court in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA, and*

Schwarz-Pharma, Inc. on June 29, 2004, made the following findings (Exhibit 7):

> "In a previous section of this opinion there is described the success which Merck achieved in maintaining the process as a trade secret to the late 1980's or early 1990's and the continuing efforts on Merck's part during the 1994 Canadian litigation to withhold the role of sodium bicarbonate in that process." (Exhibit 7 at page 16.)
>
> "Thus, before (and for a considerable time after) the conception of the invention disclosed in the '450 patent, Merck's Vasotec process had been deliberately suppressed and concealed." (Exhibit 7 at page 16.)

23. After June 29, 2004, Apotex obtained a copy of the publicly available decision in the case of *Warner-Lambert Company v. Teva Pharmaceuticals USA*, and *Schwarz-Pharma, Inc.* and learned for the first time that material omissions had been intentionally made from the Brenner declaration and false statements were made in the Brenner declaration. After obtaining the decision, Apotex obtained a copy of the transcript of Brenner's testimony from the case and learned the full extent of the material omissions that were not disclosed in the Brenner declaration.

24. Because of the material omissions that were not disclosed in the Brenner declaration and the false statement in the Brenner declaration, this Court found the Apotex patents that had been issued by the

United States Patent Office to be invalid. Not only was the ruling that the Apotex patents were invalid a grave miscarriage of justice, it was a fraud on the United States Patent system which had rightfully allowed the Apotex patents to issue.

Count I

Independent Action To Obtain Relief From Judgment

25. Apotex realleges paragraphs 1 through 24 above as if fully set forth herein.

26. By providing this Court with the Brenner declaration containing material omissions of fact that Merck suppressed, concealed and made false statements concerning Merck's use of sodium bicarbonate as a stabilizing agent up to and including the Canadian proceeding, Merck was able through its fraudulent acts to cause a grave miscarriage of justice to deprive Apotex of the Apotex patents.

27. Pursuant to Rule 60(b) of the Federal Rules of Civil Procedure, it is requested that this Court open the judgment in the 7375 action and set aside the judgment it entered in that case and find the Apotex patents not invalid.

Count II

Common Law Fraud Under Illinois Law

28. Apotex realleges paragraphs 1–27 above as if fully set forth herein.

29. The Brenner declaration filed with this Court in the 7375 action contained omissions of material fact and a false statement. Specifically, and without limitation, the Brenner declaration in the 7375 action purposely omitted the material facts that Merck had decided to maintain the critical role of sodium bicarbonate in its process for making enalapril tablets a trade secret; that Merck maintained it as a trade secret at least into the early 1990's; that the reaction involving the enalapril maleate and sodium bicarbonate had to and, that Merck knew that even if one had knowledge of the ingredients in the tablets, that knowledge would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril tablets.

30. Such omissions were material to the decisions of the District Court and the Federal Circuit Court of Appeals.

31. Brenner at the time he made the statements in the declaration presented in the 7375 action knew that Merck had made the decision to maintain the critical role of sodium bicarbonate in its process for making enalapril maleate tablets a trade secret; that Merck maintained it as a trade secret at least into the early 1990's; and, that Merck knew that even if one knew the ingredients in the tablets, that

knowledge would not reveal the critical role of sodium bicarbonate in the process of stabilizing the enalapril tablets.

32. Brenner was produced by Merck in the 7375 action as a 30 (b)(6) corporate designee. Thus, Merck itself was aware that the Brenner declaration contained omissions of material facts.

33. The Brenner declaration was provided to this Court with the intention that it would be used as a basis for finding that Merck had not suppressed or concealed the process at issue.

34. The Brenner declaration was provided to this Court with the intent that it be relied upon by the Court in finding the Apotex patents invalid.

35. The Court in the 7375 action relied upon both the statements made in the Brenner declaration and the statements omitted from that declaration in finding that Merck had not suppressed or concealed its invention and in finding the Apotex patents invalid.

36. Because of Merck's material omissions, Apotex has been damaged by having its patents held invalid and, therefore, losing substantial income that could have been derived from the licensing of the Apotex patents to Merck and others.

Count III

Tortious Interference with Prospective Economic Advantage under Illinois Law

37. Apotex realleges paragraphs 1–36 above as if fully set forth herein.

38. The Apotex patents were duly and properly issued U.S. patents prior to the Court's decision in the 7375 action.

39. Apotex had a reasonable expectation of being able choose between licensing the Apotex patents to pharmaceutical companies who wished to produce pharmaceutical products using the patented process or selling on an exclusive basis its enalapril tablets made by the Apotex patented method. Apotex had a reasonable expectation of being able to collect royalties from those licenses or profits from those sales.

40. Merck was aware that Apotex had such a reasonable expectation as Apotex was seeking to enforce its patents against Merck in the 7375 action.

41. By submitting the false and fraudulent Brenner declaration to the Court in the 7375 action, Merck purposefully and intentionally interfered with Apotex's ability and right to enter into such licenses or sell its product.

42. Merck's actions were purposely and intentionally done with the intent that this Court

rely on the misstatements and omissions in finding the Apotex patents invalid.

43. Apotex has been damaged by Merck's actions in that it has been unable to enter into any license agreements or sell any product on an exclusive basis and has thus foregone substantial income that could have been derived from licensing the Apotex patents or the exclusive sale of enalapril tablets made by the Apotex patented method.

WHEREFORE, Apotex prays for judgment and relief as follows:

a. That the judgment entered in *Merck v. Apotex*, Civil Action No. 96C7375, holding the Apotex patents invalid be vacated;

b. That Apotex receive an award of damages in an amount in excess of $75,000 to be determined by the jury for the injuries it has suffered because of the fraud committed by Merck;

c. That Apotex receive an award of damages in an amount in excess of $75,000 to be determined by the jury for the injuries it has suffered because of the tortuous [sic] interference with prospective economic advantage.

d. That Merck pay all of Apotex's costs in bringing this litigation.

e. That Apotex receive an award for punitive damages to be determined by the jury.

f. Grant all such other relief as the Court deems just and equitable.

Jury Demand

Apotex requests trial by jury for all matters that are triable by jury.

Dated: March 24, 2005

By: /s/ Robert B. Breisblatt

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